

2. P01:Pathology Completeness

Chapter 2

2.1 Overview

Pathology report P01, Pathology Completeness, summarizes the completeness of pathology data collection for a study by evaluating data collected for each animal against specific data criteria. Instances of each violation are tallied and reported for each of the criteria. The resulting output is displayed by treatment group and data collection criteria.

2.1.1 Data Criteria

- The animal is in a treatment group which has Protocol Required Tissues (PRTs) and one or more of those PRTs has no pathology data collected against it.
- The animal is in a treatment group which has no PRTs and the animal has **not been** marked 'Not Examined'.
- The animal is in a treatment group which has PRTs and the animal **has** been marked 'Not Examined'.
- The animal has microscopic observations but is in a treatment group for which there is no PRT set.
- The animal has PRTs, is on a chronic study, has a removal reason of Natural Death, Moribund Sac, MSAC or Accidentally Killed and does not have a primary or undetermined cause of death recorded.

The P01 report also lists removal reasons used on the study but not included in the any of the PRT sets.



No Extended Selections are available for this report.

Animals removed for the reason of Other, Missing, Wrong Sex or SSAC w/o Necropsy are automatically excluded from this report since they require no pathology data collection.

Each report contains:

- Treatment Group Description
- Sex
- PRTs Defined

- Total Animals per treatment group
- Each of the data collection criteria (See Table 2-1 for details)
- Removal Reasons used that are not in the PRT set
- PRT sets
- Specific animals meeting the criteria and the specific reason the animal was identified

2.2 P01 Pathology Completeness Description

TDMS No. 99999 - 02 Test Type: CHRONIC Route: GAVAGE Species/Strain: MICE/B6C3F1			P01: PATHOLOGY COMPLETENESS TETRABROMOBISHPHENOL A CAS Number: 79-94-7			Date Report Requested: 07/16/2009 Time Report Requested: 15:39:52 First Dose M/F: 12/15/05 / 12/14/05 Lab: BAT			# Animals with obs but no PRTs	
PRTs Defined									# Animals with PRTs but no data	
SUMMARY										
TREATMENT GROUP		SEX	PRTS DEFINED	TOTAL ANIMALS	PRT WITHOUT DATA	NOT EXAMINED REQUIRED	PRT WITH NOT EXAMINED	PATHOLOGY DATA WITHOUT PRTS	NO QUALIFYING COD PRESENT	# Animals without primary COD
Treatment Group	1 0 mg/kg	M	Yes	50	2	0	1	0	0	
	2 10 mg/kg	M	No	50	0	0	0	0	0	
	3 100 mg/kg	M	Yes	50	0	0	0	0	0	
	4 1000 mg/kg	M	Yes	50	0	0	0	0	0	
Sex	5 20 mg/kg	M	Yes	50	3	0	1	0	2	# Trt Groups no PRTs & animals not marked 'not examined'
	6 200 mg/kg	M	No	50	0	1	0	0	0	
	7 2000 mg/kg	M	No	50	0	0	0	50	0	
	8 30 mg/kg	M	Yes	50	0	0	0	0	0	
Removal Reasons not in PRTs	9 300 mg/kg	M	Yes	50	0	0	0	0	0	
	10 3000 mg/kg	M	Yes	50	0	0	0	0	0	
	11 40 mg/kg	M	Yes	50	0	0	0	0	0	
	12 400 mg/kg	M	Yes	50	0	0	0	0	0	
Total # Animals in Trt Grp	13 4000 mg/kg	M	Yes	50	0	0	0	0	0	
	14 50 mg/kg	M	Yes	50	0	0	0	0	0	# Animals with obs but marked examination not required
	15 500 mg/kg	M	Yes	50	0	0	0	0	0	
	16 5000 mg/kg	M	Yes	50	0	0	0	0	0	
REMOVAL REASONS USED THAT ARE NOT IN THE PRTS: DACC, Harvest										

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Figure 2-0: P01 Report Summary page

Table 2-1 lists and describes the fields of the P01- Pathology Completeness report.

Field	Description
Treatment Group	<ul style="list-style-type: none"> This field identifies the treatment group number and the associated treatment group description.
Sex	<ul style="list-style-type: none"> This field identifies the sex of animals within the treatment group. Options are Male or Female.
PRTs Defined	<ul style="list-style-type: none"> This field identifies whether or not the treatment group has a PRT set defined. Options are Yes or No.
Total Animals	<ul style="list-style-type: none"> This field identifies the number of animals initially assigned to the treatment group at the start of the study.
PRT Without Data	<ul style="list-style-type: none"> This field is a tally of the number of animals in a treatment group that has Protocol Required Tissues (PRTs) and one or more of those PRTs has no data collected.
Not Examined Required	<ul style="list-style-type: none"> This field is a tally of the number of animals in a treatment group if the treatment group has no PRTs and the animal has not been marked 'Not Examined'.
PRT with Not Examined	<ul style="list-style-type: none"> This field is a tally of the number of animals in a treatment group if the treatment group has PRTs and the animal has been marked 'Not Examined'.
Pathology Data without PRTs	<ul style="list-style-type: none"> This field is a tally of the number of animals in the treatment group with microscopic observations, but the treatment group has no PRT set defined.
No Qualifying COD Present	<ul style="list-style-type: none"> This field is a tally of the number of animals in a treatment group that has PRTs, the study is chronic, the animal has a removal reason of Natural Death, Moribund Sac, MSAC or Accidentally Killed, but it does not have a primary or undetermined cause of death.
Removal Reasons Used That Are Not In The PRTs	<ul style="list-style-type: none"> This field lists any removal reasons used on the study but not included in any of the study PRT sets.

Table 2-1: P01-Pathology Completeness Summary page field descriptions

TDMS No. 99999 - 02 Test Type: CHRONIC Route: GAVAGE Species/Strain: MICE/B6C3F1	P01: PATHOLOGY COMPLETENESS TETRABROMOBISHPHENOL A CAS Number: 79-94-7	Date Report Requested: 07/16/2009 Time Report Requested: 15:39:52 First Dose M/F: 12/15/05 / 12/14/05 Lab: BAT
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PRT grouped by Trt Grp, Tissues, and Removal Reasons	PRT Set	Treatment Groups: 1, 3, 4, 8, 10, 11 Removal Reasons: ACCK, NATD, MSAC, SSAC, TSAC Tissues: Adren Cortex, Adren Medulla, Bone, Brain, Epididymis, Esophagus, Gallbladder, Harderian Gl, Heart, Int Lg Cecum, Int Lg Rectum, Int Sm Duoden, Int Sm Ileum, Islets Panc, Kidney, Liver, Lung, Lym Node Mesen, Mammary Gl, Pancreas, Pituitary Gl, Preputial Gl, Testes, Thymus, Trachea, Urin Bladder
Animal Tissue detail	Animal	Tissues
	00101	Lung
	00102	Adren Medulla, Bone, Brain, Epididymis, Esophagus, Gallbladder, Harderian Gl, Heart, Int Lg Cecum, Int Lg Rectum, Int Sm Duoden, Int Sm Ileum
	00081	Not Examined
PRT Set		
Treatment Groups: 12, 13, 14, 15, 16 Removal Reasons: ACCK, MSAC, NATD, SSAC, TSAC Tissues: Adren Medulla, Bone, Brain, Epididymis, Gallbladder, Harderian Gl, Heart, Int Lg Cecum, Int Lg Rectum, Int Sm Duoden, Int Sm Ileum, Islets Panc, Kidney, Liver, Lung, Lym Node Mesen, Mammary Gl, Pancreas, Pituitary Gl, Preputial Gl, Testes, Thymus, Trachea		
No Problem Animals		
PRT Set		
Treatment Groups: 5, 9 Removal Reasons: ACCK, MSAC, NATD, SSAC, TSAC Tissues: Adren Cortex, Adren Medulla, Bone, Brain, Epididymis, Gallbladder, Harderian Gl, Heart, Int Lg Cecum, Int Lg Rectum, Int Sm Duoden, Int Sm Ileum, Islets Panc, Kidney, Liver, Lung, Lym Node Mesen, Mammary Gl, Pancreas, Pituitary Gl, Preputial Gl		
Animal	Tissues	
00501	Lung	
00502	Adren Medulla, Bone, Brain, Epididymis, Int Lg Rectum, Int Sm Duoden	
00503	Missing Cause Of Death	
	Heart	
00513	Not Examined	
00519	Missing Cause Of Death	
*** END OF REPORT ***		
Not Examined - Animals that have PRTS associated with them but the animal has been marked Not Examined		
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Figure 2-1: P01: Pathology Completeness (cont.)

Table 2-1 lists and describes the fields of the P01-Pathology Completeness report.

Field		Description
PRT Set		<ul style="list-style-type: none"> • Protocol required tissues set uniquely grouped by treatment group, removal reason and tissues.
	Treatment Group	<ul style="list-style-type: none"> • The treatment group numbers for the treatment groups to which this PRT set applies.
	Removal Reasons	<ul style="list-style-type: none"> • The removal reasons included as part of this PRT set.
	Tissues	<ul style="list-style-type: none"> • The tissues in the pathology protocol that are part of this PRT set.
Problem Animal Identification Section		<ul style="list-style-type: none"> • Animals tallied in the categories of PRT Without Data, PRT With Not Examined and No Qualifying COD Present are listed in this section. • For PRT Without Data, the tissue for which no data has been collected is displayed next to the animal number. • If there are no problems, 'No Problem Animals' is displayed.
Footnote		<ul style="list-style-type: none"> • This dynamic footnote is only displayed when the criteria has been met.

Table 2-2: P01-Pathology Completeness field descriptions

2.3 Application and Display of Criteria

This section documents how each of the criteria are present in the P01 report based on data within Figures 2-1 and 2-2.

- 1) **PRT Without Data:** In Figures 2-1 and 2-2, this is demonstrated in treatment groups 1 and 5. As shown in the animal list under the PRT set containing treatment group 1, the two animals identified are listed along with the tissues for which no data was collected (animals 101 and 102). As shown in the animals list under the PRT set containing treatment group 5, the animals identified are listed along with the tissues for which no data was collected (animals 501, 502 and 503).
- 2) **Not Examined Required:** In Figure 2-1, this is demonstrated in treatment group 6. In these cases, the animal number is not displayed with any PRT set. This would only be identified in the Summary. The PRTs Defined column is generally 'No' for this treatment group. There are cases in which the animal is removed for a removal reason which is not part of the treatment group PRT set. In this case, the PRTs Defined column will be 'Yes'.

- 3) **PRT With Not Examined:** In Figures 2-1 and 2-2, this is demonstrated in treatment groups 1 and 5 which have PRTs and at least one animal within that treatment group has been marked 'Not Examined'. This would be displayed on the Summary under the 'PRT With Not Examined' column and if you look at the animals list, under the PRT sets containing treatment groups 1 and 5, the animal(s) identified are listed along with the words 'Not Examined'.
- 4) **Pathology Data Without PRTs:** In Figure 2-1, this is demonstrated in treatment group 7 where at least one animal within the treatment group has microscopic observations but is in a treatment group for which there is no PRT set. This would only be displayed in the Summary with the PRTs Defined listed as 'No' and a number of animals in the 'Pathology Data Without PRTS'.
- 5) **No Qualifying COD Present:** In Figures 2-1 and 2-2, this is demonstrated in treatment group 5. In this case, an animal has PRTs, is on a chronic study, has a removal reason of Natural Death, Moribund Sacrifice, MSAC or Accidentally Killed and does not have a primary or undetermined cause of death. This would be displayed in the Summary under the 'No Qualifying COD Present' and if you look at the animal list under the PRT set containing treatment group 5, the animal identified is listed along with the words 'Missing Cause of Death'.



‘*END OF REPORT***’ displays at the bottom of the final page of the report.**